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FEDERAL TRADE COMMISSION

[File No. 151 0202]

Lupin Ltd., Gavis Pharmaceuticals LLC, and Novel Laboratories, Inc.; Analysis to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before March 22, 2016.

ADDRESSES: Interested parties may file a comment at

<https://ftcpublic.commentworks.com/ftc/lupingavisnovelconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY**

INFORMATION section below. Write “In the Matter of Lupin Ltd., Gavis Pharmaceuticals LLC, and Novel Laboratories, Inc. - Consent Agreement; File No. 151-0202” on your comment and file your comment online at

<https://ftcpublic.commentworks.com/ftc/lupingavisnovelconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write “In the Matter of Lupin Ltd., Gavis Pharmaceuticals LLC, and Novel Laboratories, Inc. - Consent Agreement; File No. 151-0202” on your comment and on the envelope, and mail your comment to the following

address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kari Wallace, (202-326-3085), Bureau of Competition, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for February 19, 2016), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 22, 2016. Write “In the Matter of Lupin Ltd., Gavis Pharmaceuticals LLC, and Novel Laboratories, Inc. - Consent Agreement; File No. 151-0202” on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).¹ Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at

<https://ftcpublic.commentworks.com/ftc/lupingavisnovelconsent> by following the instructions

¹ In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR § 4.9(c).

on the web-based form. If this Notice appears at <http://www.regulations.gov/#!/home>, you also may file a comment through that website.

If you file your comment on paper, write “In the Matter of Lupin Ltd., Gavis Pharmaceuticals LLC, and Novel Laboratories, Inc. - Consent Agreement; File No. 151-0202” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 22, 2016. You can find more information, including routine uses permitted by the Privacy Act, in the Commission’s privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Lupin Ltd. (“Lupin”) and Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. (collectively “Gavis”) that is designed to remedy the anticompetitive effects resulting from Lupin’s acquisition of Gavis. Under the terms of the proposed Consent Agreement, the parties are required to divest all of

Gavis's rights and assets related to generic doxycycline monohydrate capsules and generic mesalamine extended release ("ER") capsules to G&W Laboratories ("G&W").

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order ("Order").

Pursuant to Purchase and Sale Agreements dated July 23, 2015, Lupin plans to acquire Gavis Pharmaceuticals LLC and Novel Laboratories, Inc. for approximately \$850 million (the "Proposed Acquisitions"). Gavis and Novel are related companies. Novel researches, develops and manufactures generic pharmaceutical products, which Gavis markets and sells. The Commission alleges in its Complaint that the Proposed Acquisitions, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening current competition in the market for generic doxycycline monohydrate capsules and future competition in the market for generic mesalamine ER capsules in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisitions.

I. The Products and Structure of the Markets

The Proposed Acquisitions would reduce the number of current suppliers in the market for generic doxycycline monohydrate capsules and reduce the number of future suppliers in the market for generic mesalamine ER capsules.

Generic doxycycline is an antibiotic used for treating a variety of different bacterial infections, including respiratory infections, urinary tract infections, severe acne, skin and skin structure infections, Lyme disease, and anthrax. Generic doxycycline monohydrate is available in four strengths: 50 mg, 75 mg, 100 mg, and 150 mg. Gavis and Lupin both market three of the four strengths, 50 mg, 75 mg, and 100 mg. Both Lupin and Gavis are recent entrants into the generic doxycycline monohydrate market; Lupin launched its product in March 2014, while Gavis launched its product at the end of July 2015. Endo International plc, Allergan, Inc., and Sun Pharmaceutical Industries Ltd. also offer generic doxycycline monohydrate products in the United States. All five companies offer the 100 mg strength, but only four companies offer the 50 mg and 75 mg strengths.

Mesalamine ER capsules are used to treat ulcerative colitis. Valeant Pharmaceuticals markets Apriso, the branded version of the product, which is available in a 375 mg formulation. No generic version of mesalamine ER capsules is currently available in the United States. Lupin and Gavis are developing generic mesalamine ER capsules products, and are two of a limited number of suppliers capable of entering the market in the near future.

II. Entry

Entry into the two relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisitions. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

III. Effects

The Proposed Acquisitions likely would cause significant anticompetitive harm to consumers by eliminating current competition between Lupin and Gavis in the market for generic doxycycline monohydrate capsules. Market participants characterize generic doxycycline monohydrate capsules as commodity products. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The Proposed Acquisitions would combine two of only four companies offering the 50 mg and 75 mg strengths of generic doxycycline monohydrate capsules, likely leading consumers to pay higher prices.

In addition, the Proposed Acquisitions likely would cause significant anticompetitive harm to consumers by eliminating future generic competition that would otherwise have occurred in the mesalamine ER capsule market if Lupin and Gavis remained independent. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisitions due to the elimination of an additional independent entrant in the market for generic mesalamine ER. Customers and competitors expect that the price of this pharmaceutical product will decrease with new entry by Lupin and Gavis. Thus, absent a remedy, the Proposed Acquisitions will likely cause U.S. consumers to pay significantly higher prices for generic mesalamine ER.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisitions in the markets at issue by requiring Gavis to divest all its rights and assets relating to doxycycline monohydrate capsules and mesalamine ER to G&W. Founded in 1919, G&W is a privately held, family-owned, generic pharmaceutical company. G&W develops,

manufactures, sells, and distributes generic pharmaceuticals and over-the-counter products within the United States.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisitions. If the Commission determines that G&W is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to G&W and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed D&O requires that Lupin supply G&W with generic doxycycline monohydrate capsules for two years while Lupin transfers the manufacturing technology to G&W's facility. To ensure the success of the generic doxycycline monohydrate capsules divestiture, the proposed D&O requires Lupin to provide transitional services to assist G&W in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Gavis, and advice and training from knowledgeable employees of the parties.

To assist G&W with completing the regulatory work and setting up and validating the manufacturing for the generic mesalamine ER product, G&W will enter into a consulting agreement with Gavis's current CEO, Dr. Veerappan Subramanian, who will not be employed by Lupin post-transaction. Dr. Subramanian is the founder of Gavis and has previously served as the chief scientist for the company. He has been involved with the development and

manufacturing of the generic mesalamine ER product since the company started the formulation.

G&W will also inherit Gavis's ongoing patent litigation related to mesalamine ER. G&W

intends to retain Gavis's current counsel to continue the litigation.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement,

and it is not intended to constitute an official interpretation of the proposed Order or to modify

its terms in any way.

By direction of the Commission.

Donald S. Clark,
Secretary.

[FR Doc. 2016-04040 Filed: 2/24/2016 8:45 am; Publication Date: 2/25/2016]